

-7 -

WE CLAIM:

1. A method of detecting osteolysis in a patient comprising:
 - (a) obtaining a sample containing lymphocytes from the patient; and
 - 5 (b) determining the amount of CD4⁺CD25⁺ regulatory T cells wherein an increase in regulatory T cells as compared to a control indicates that the patient has osteolysis.
2. A method of detecting osteolysis according to claim 1 comprising:
 - 10 (a) obtaining a sample containing lymphocytes from the patient; and
 - (b) determining the amount of CD4⁺CD25⁺ regulatory T cells as a percentage of the total CD4⁺ lymphocytes in the sample, wherein a level of regulatory T cells of greater than 45% indicates that the patient has osteolysis.
- 15 3. A method according to claim 2 wherein the regulatory T cells are present in an amount of greater than 50% of the total lymphocytes in the sample.
- 20 4. A method according to claim 2 wherein the regulatory T cells are present in an amount of greater than 60% of the total lymphocytes in the sample.
5. A method according to claim 2 wherein the regulatory T cells are
25 present in an amount of greater than 70% of the total lymphocytes in the sample.
6. A method according to any one of claims 1-5 wherein the sample is peripheral blood.
- 30 7. A method according to claim 6 wherein the regulatory T cell has the phenotype CD3⁺CD4⁺CD25⁺CD45RA⁺.

-8 -

8. A method according to claim 7 wherein the regulatory T cells are non-activated (CD80/86⁻).
- 5 9. A method according to claims 1-6 wherein the sample is synovial fluid, synovial tissue or interface tissue between the failed component and the bone defect.
10. A method according to claim 9 wherein the regulatory T cells are
10 activated (CD80/86⁺).
11. A method according to any one of claims 1-10 wherein the osteolysis is a result of total hip replacement.
- 15 12. A method according to any one of claims 1-10 wherein the osteolysis is a result of primary or metastatic bone cancer.
13. A method according to any one of claims 1-10 wherein the osteolysis is a result of a metabolic bone disease.
- 20 14. A method according to claim 13 wherein the metabolic bone disease is Paget disease.
15. A kit for detecting osteolysis comprising reagents for detecting
25 CD4⁺CD25⁺ regulatory T cells as well as instructions for the use of the kit.
16. A kit according to claim 15 wherein the reagents comprise antibodies that bind to CD4 and antibodies that bind to CD25.